Clinical Trials Shed Light on Minority Health

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Why is this important?
Ensuring meaningful representation of minorities in clinical trials for regulated medical products is fundamental to FDA's regulatory mission and public health, says Jonca Bull, M.D., director of the agency's Office of Minority Health (OMH). Racial and ethnic minorities include African American, American Indian, Alaska Native, Asian American, Hispanic American, Native Hawaiian and Pacific Islander communities.

OMH project manager Christine Merenda, M.P.H., R.N. explains that clinical trials are the proving ground for new drugs, vaccines and devices. They provide the data that will determine whether FDA approves a manufacturer's application for marketing approval.

"Potential racial, ethnic and other differences in response to drugs are important to FDA's efforts to help ensure that the safety and effectiveness of drugs are studied in all people who will use the products once they are approved," she says.

April is Minority Health Month

FDA's Office of Minority Health (OMH) helps identify agency actions that can help reduce disparities in health and health care. There will be several Consumer Updates this month highlighting the work of this office:

- The work being done to lessen health disparities
- The importance of including minorities in clinical trials
- Research and collaborations

To read these Consumer Updates, go to: *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm347896.htm*

And to learn more about OMH Director Jonca Bull's perspective on her office's top priorities, go to: *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm335589*

Considering Genetic Differences
Bull explains that there are biological differences in how people process drugs. For example, variations in genetic coding can make a cancer treatment more toxic in one ethnic group than it would be in another.

These variations can make also make drugs like antidepressants and blood-pressure medications less effective in one group than another.

Getting more data on these differences is essential for FDA to truly know that a medical product will truly work and be safe for all patients, Bull says.

Members of minority groups may be more vulnerable to certain diseases. "We know, for example, that African-Americans and Hispanics have higher rates of diabetes, HIV/AIDS, obesity and cardiovascular disease," says Bull. Native Americans and Asians have been shown to have higher rates of hepatitis, while Hispanics are disproportionately affected by diabetes.

But historically, both women and minorities have been under-represented in clinical trials. For example, according to a 2011 report from the conference "Dialogues on Diversifying Clinical Trials," sponsored by FDA's Office of Women' s Health and the Society for Women's Health Research and supported by OMH:

- African Americans represent 12% of the U.S. population but only 5% of clinical trial participants;
- Hispanics make up 16% of the population but only 1% of clinical trial participants; and
- "Men make up more than two-thirds of the participants in clinical tests of cardiovascular (heart and blood vessel) devices?"

At the conference, more than 200 representatives from government and industry came together with patient advocates and the scientific community to discuss strategies for increasing the participation of women and minorities in clinical trials.

Why the Disparity?

Bull says there are different reasons why minorities have been under-represented in clinical trials.

One reason may be a lack of trust because of past abuses, Bull says. One notorious example was the Tuskegee Syphilis Study, experiments conducted between 1932 and 1972 by the U.S. Public Health Service. Health officials recruited poor black sharecroppers in Alabama to study the natural progress of syphilis. However, while the study was in progress, penicillin was discovered to treat syphilis. The study was not stopped and the men were not treated with penicillin that could have cured them.

According to a recent university study, however, this attitude seems to be changing. The study was designed to learn the health concerns and research perceptions among under-represented groups. When asked about their overall interest in medical research, 91 percent of African-Americans expressed interest in participating.

Nonetheless, recruiting people to participate in clinical trials—no matter what race or ethnicity—is difficult in general, Bull notes. FDA works to protect participants in clinical trials and to ensure that people have reliable information as they decide whether to join a clinical trial.

There are many benefits to minority participation for researchers that extend, in a larger sense, to society. Minority participation helps researchers find better treatments and better ways to fight such diseases as cancer, diabetes, heart disease and HIV/AIDS. In addition, it uncovers differences by gender, race, and ethnicity that may be important for safe and effective use of therapies.

Safeguards and Resources

Safeguards for clinical trial participants include oversight by institutional review boards (IRBs), composed of at least five members, including scientists, doctors, and lay people. IRBs ensure that appropriate steps are taken to protect the rights and welfare of participants as subjects of research.

Though it's too soon to tell, Bull says that the FDA Safety and Innovation Act (FDASIA) signed into law by President Obama in July 2012 could have a helpful effect in supporting efforts to enhance minority participation in clinical trials. FDASIA requires that FDA report to Congress by July 9, 2013 on the diversity of participants in clinical trials and the extent to which safety and effectiveness data based on such factors as sex, age, race and ethnicity are included in applications submitted to FDA.

Based on these findings, FDA and others involved in clinical research will be able to identify needs and opportunities to increase minority representation, says Bull.

In the meantime, Bull encourages consumers to take a more proactive approach. If you're undergoing treatment and your condition is not improving, she says, you may want to talk to your health care professional about the availability of clinical trials that address your condition.

FDA also has information at fda.gov (*http://www.fda.gov*) with information about participating in clinical trials (*http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ParticipatinginClinicalTrials/default.htm*) and links to an array of resources. And clinicaltrials.gov (*http://www.clinicaltrials.gov*) is another resource from the National Institutes of Health.

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